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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,370	08/25/2008	**Yatendra Kumar**	RLL-496US	3246

26815 7590 01/05/2011

Ranbaxy Inc.
Intellectual Property Department
600 College Road East
PRINCETON, NJ 08540

EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	

NOTIFICATION DATE	DELIVERY MODE
01/05/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

general.ip.mailbox@ranbaxy.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,370	KUMAR ET AL.	
	Examiner	Art Unit	
	EMILY BERNHARDT	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 22-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Applicant's election without traverse of III in the reply filed on 11/1/10 is acknowledged.

Claims 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The term "substantially pure" appearing in independent claims 30-31 is of indeterminate scope. While remaining claims report a lower purity limit, it is not clear which of these values is being relied on or something else. Note the following quote taken from Cole v. Sears, Roebuck & Company, 187 USPQ 65 at 66:

The patent law does not require a prospective inventor to search so far in attempting to determine the scope of a patent and the areas left open for inventive inquiry. Section 112 provides that it is the claims that shall *particularly point out* and *distinctly* claim the subject matter of the patentee's invention. Certainly, terms used in the claims can gain meaning from the specifications or from the knowledge attributable to one skilled in the art. But a prospective inventor is required to go no further in attempting to determine the invention claimed and the areas foreclosed to future enterprise.

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"In our view of this case, the Appellants ask this Court to ignore the precision of definition required of them by the statute. As the Supreme Court noted in Union Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 63 S.Ct. 165, 87 L.Ed. 232, 55 USPQ 381 (1942), to allow claims "so indefinite as not to give the notice required by the statute would be in direct contravention of the public interest which Congress * * * recognized and sought to protect." In that case the Court considered a product patent where the distinction from the prior art was a matter of degree. The Court rejected terms, such as "substantially pure", "commercially uniform", and "comparatively small", that gave no standard for comparison or were so indefinite as to have no established meaning to one skilled in the art. Kaiser Industries Corp. v. McLouth Steel Corp., supra at 50-51, 158 USPQ at 579."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-21 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Busch (WO'246, cited by applicants). Busch is directed to the obtention of high purity pharmaceutical grade ziprasidone as well as its salt forms including the HCl salt. The publication describes a process to remove a known impurity, namely the 6-des Cl analog. Said process is taught on pp.6-7 in which repeated recrystallization(s) or reslurrying of the impure composition(s) is performed until a minimum level of the impurity is detected ($\leq$.28%). By this process the impurity in the "ziprasidone" compositions are at **least 1000ppm or less**. This corresponds to 0.1% or less which meets applicants' purity levels. The reference also teaches the use of said compounds for schizophrenia,etc. as first described in US 4,831,031. See examples 1 and 2 which prepares the free base and HCl salt as the monohydrate. While actual percentages based on HPLC is not set forth in these examples (although HPLC is relied on to assess the amount of impurity present as discussed in previous pages), it is well settled that applicants must show that their compounds are really different from the ones prepared

in the prior art. MPEP 2112 states:

"SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

In this case, the "unknown property" is the particular claimed purity limitations.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, "There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (page 1253). The "properties" aspect of that statement applies here. However, given the teachings of Busch it is reasonable to assume the amount of impurity present in the working examples met the minimum requirements (i.e. < 0.1%) dictated by Busch.

Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Reddy (US'354, cited by the examiner). The US patent publication is applied as of its parent filing date of 6/14/04. Claim 20 is not entitled to 119 benefit of earliest priority since the 99.8%, lower limit range is not described therein but rather 99.75%. Remaining claims are entitled to earlier 119 benefit and thus Reddy is not prior art for these claims. It

describes the preparation of "pure" ziprasidone base. See examples 6-7. While purity levels are not set forth in these examples, the same remarks made in the above 102 rejection over Busch apply here as well.

Claims 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Busch (US'918 cited by applicants). Busch describes the preparation of ziprasidone free base which is used as a synthetic precursor for making a mesylate salt. See eg.1. Note the purity analysis via HPLC was reported to be 101.5% ±2%. Thus conservatively the purity could be 99.5% or higher employing the purification process taught by Busch.Thus the same remarks made in the above 102 rejection over Busch apply here as well.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-21 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Busch (WO'246), Reddy (US'354), Busch (US'918) and Arenson (US'366), Bowles (US'366) and Busch (US'846). The three newly cited references were cited by applicants. The newly cited references also teach either the free base or HCl salt can be prepared in very high purity. See in Arenson eg.10 which shows the production of the free base as 99.7% pure after a double recrystallization. In Bowles see eg.1 for preparation of the HCl salt as 99.5% pure. In Busch see eg.2 for the preparation of ziprasidone free base as 99.7%. These and the anticipatory

references, if they turn out not to meet all the claim limitations, are nevertheless obvious variants of the free base and HCl salt claimed herein since differences in purity for otherwise old compounds does not impart patentability thereto absent evidence of unexpected properties. Note In re Volwiler 46 USPQ 137. Thus it would have been obvious to one skilled in the art at the time the instant invention was made to prepare purer forms of ziprasidone base and HCl salt by one or more processes taught in the art applied herein for use as high grade pharmaceuticals given the many teachings directed at obtaining such compounds in high yield as well as purity.

Claims 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowles (US'366). The patent teaches the synthesis of 99.5% pure HCl salt for use as a pharmaceutical for treating schizophrenia, among other uses. As there is no specific purity limitation in these claims, the claims read on the teachings of Bowle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/
Primary Examiner, Art Unit 1624

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